Remarks

Claims 1 and 8-11 are pending. Claims 2-7 were previously cancelled without prejudice to or disclaimer of the underlying subject matter. Claims 8-11 have been amended. Support for the foregoing amendment can be found throughout the specification and claims as originally filed, for example on page 19, line 23 through page 20, line 12. No new matter enters by way of the foregoing amendment.

I. Rejection under 35 U.S.C. §101

Claims 1 and 8-11 stand rejected under 35 U.S.C. § 101, because the claimed invention allegedly lacks patentable utility. Final Action at page 2. Applicants respectfully traverse this rejection.

The specification provides a specific, substantial, and credible utility for SEQ ID NO: 1 and complements thereof. For example, as the Examiner acknowledges, the specification clearly asserts that SEQ ID NO: 1, contains sequences that encode for a protein with significant sequence identity to a protein with Src homology 3 (SH3) domain profile. *See, e.g.,* specification at page 92, Table 1, and the sequence listing. The Examiner argues, however, that "the specification has not established that the presence of the SH3 domain profile imparts a specific biological activity to the encoded protein." Final Action at page 3. The skilled artisan would have understood the role of proteins having SH3 domains, for example in signal transduction. *See, e.g.*, Sparks, *et al.*, Proc. Natl. Acad. Sci. 93:1540-1544 (1996) (a copy of which is made of record). In addition, the specification also discloses that the nucleic acid molecules can be used to monitor the expression of such proteins, for example in a cell. *See, e.g.,* specification at page 56, line 25

through page 57, line 19, and Table 1. One of ordinary skill in the art would recognize that the claimed nucleic acid molecules have utility, for example, to identify markers and isolate promoters associated with the proteins disclosed as encoded by SEQ ID NO: 1, including proteins having SH3 domain profiles. These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

The "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility...where specific benefit exists in currently available form." *Brenner v. Manson*, 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met this part of the bargain – the present specification discloses nucleic acid molecules which, in their current form, provide at least one specific benefit to the public, for example, encoding a protein having an SH3 domain profile, or detecting a nucleic acid molecule encoding an SH3 protein including signal transduction proteins. *See, e.g.* Specification at page 16, line 25 through page 17, line 9, Table 1, and Sparks, *et al.* This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit.

The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide <u>one</u> identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The Federal Circuit has recently provided guidance as to the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir, 2005). First, the Court indicated that the specification disclose "that an invention is useful to the public as disclosed in its current form." *Id.* at 1371. Second, the Court further noted that the specification "also show that that claimed invention can be used to provide a well-defined and particular benefit." *Id.* Applicants have provided nucleic acid sequences which are identified in the specification to correlate to genes having SH3 domain profiles. Such a correlation is sufficient to satisfy the utility standard. *Id.*

The present specification discloses specific and substantial uses for the claimed nucleic acid molecules, including use to encode proteins having SH3 domains (*see, e.g.,* specification at page 16, line 25 through page 17, line 9, page 30, line 8 through page 31, line 12, and Table 1 and the sequence listing); use to identify polymorphisms related to such proteins (*see, e.g.,* specification at page 49, line 24 through page 56, line 24); use to transform plants to modify the expression of such genes (*see, e.g.,* specification at page 61, line 1 through page 80, line 11); and to monitor the expression of such proteins or mRNA associated with those proteins (*see, e.g.,* specification at page 56, line 25 through page 57, line 19). Such disclosure provides a well-defined benefit that is useful in its current form. *Cf. In re Fisher,* 421 F.3d at 1373 (noting that as of the filing date the underlying genes had no known functions).

The Examiner argues, however, that "the specification has not established that the presence of the SH3 domain profile imparts a specific biological activity to the encoded protein." Final Action at page 3. As set forth above, one of ordinary skill in the art

would recognize that the claimed nucleic acid molecules have utility, for example, to encode proteins having SH3 domains, upon reading the present specification. Moreover, the skilled artisan would recognize that proteins having such SH3 domain profiles can be involved in signal transduction pathways. *See, e.g.* Sparks, *et al.*, Proc. Natl. Acad. Sci. USA, 93:1540-1544 (1996). These utilities are immediately apparent for the claimed nucleic acid molecules without further research.

An examiner must accept a utility by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). "More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such as assertion." Federal Register 66(4):1096, Utility Guidelines (2001). "[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996). "An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof." M.P.E.P. § 2107.03, at page 2100-43. Applicants have demonstrated such a reasonable correlation.

The claimed nucleic acid molecules have been asserted to encode proteins having SH3 domains. The specification provides ample correlation between the claimed nucleic acid molecules and the recited proteins having SH3 domains. Proteins having such SH3

domains are known to play important roles in signal transduction. *See, e.g.*, Sparks, *et al.*, Abstract. Accordingly, the assertion of the use of the claimed nucleic acid molecules to encode the recited protein or fragment thereof satisfies the utility requirement of 35 U.S.C. § 101.

Applicants have disclosed a specific, substantial and credible utility for the claimed nucleic acid molecules. Any one of these utilities is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

II. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claims 1 and 8-11 stand rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Final Action at page 5. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

The Examiner also alleges that "the specification has not adequately taught one of skill in the art how to use nucleic acids [that] comprise a nucleic acid which has 90%-100% identity with SEQ ID NO: 1." Final Action at page 5. The Examiner argues that "it appears that claims 8-11 encompass nucleic acids containing fragments having 90%-100% identity with a fragment of SEQ ID NO: 1 and flanked by sequences of unspecified length." *Id.* Applicants submit that the claims do not recite to fragments of the recited

nucleic acid. The Examiner has applied an untenable interpretation of the claims to cover small fragments of the claimed sequences. Although Applicants disagree, to facilitate prosecution, claims 8-11 have been amended to recite that the nucleic acid molecules have the recited percent identity with "the nucleic acid sequence of SEQ ID NO: 1 or complement thereof." Applicants contend that the rejection that "the specification has not adequately taught one of skill in the art how to use nucleic acids" has been overcome by the arguments set forth above regarding utility of the claimed sequences. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

III. Rejection under 35 U.S.C. § 112, first paragraph, Written Description

Claims 8-11 stand rejected under 35 U.S.C. § 112, first paragraph because the claimed subject matter allegedly was "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." Final Action at page 10. Applicants respectfully traverse this rejection.

The Examiner, acknowledges that "[n]ucleic acids consisting of SEQ ID NO: 1 and proteins encoded by SEQ ID NO: 1 meet the written description requirement." Final Action at page 10. However, the Examiner argues that Applicants have allegedly not described the claimed genus of nucleic acids having 90-99% identity with SEQ ID NO: 1.[1] *Id.* The basis for the Examiner's rejection is that because the "claims do not clarify

[1] Applicants note that the Examiner also argues that Applicants have allegedly not described "the claimed genus of nucleic acids that specifically hybridize with SEQ ID NO: 1." Final Action at page 10. It is noted however, that claims 2 and 3 were previously cancelled without prejudice to or disclaimer of the underlying subject matter. It appears that the Examiner maintained the rejection directed toward the subject matter of cancelled claims 2 and 3 in error.

whether such nucleic acids share identity over the full length of SEQ ID NO: 1...it appears that claims 8-11 encompass nucleic acids containing fragments having 90%-100% identity with a fragment of SEQ ID NO: 1 and flanked by sequences of unspecified length and identity." *Id.* at pages 10-11. The Examiner therefore concludes that "the claims include nucleic acids and proteins from other species, naturally-occurring and non-naturally occurring mutated nucleic acids, allelic variants, and splice variants and fragments of said nucleic acids." *Id.* at page 8. Apparently, the Examiner contends that "the specification does not exemplify any specific nucleic acids which have 90-99% identity with SEQ ID NO: 1." *Id.* at page 11. Applicants respectfully disagree.

The Examiner has applied an untenable interpretation of the claims to cover small fragments of the claimed sequences. Although Applicants disagree, to facilitate prosecution, claims 8-11 have been amended to recite that the nucleic acid molecules have the recited percent identity with "the nucleic acid sequence of SEQ ID NO: 1 or complement thereof."

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventor actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventor had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would,

after reading the present specification, understand that Applicants had possession of nucleic acid molecules SEQ ID NO: 1, and sequences with the recited percent identity and therefore, the claimed invention.

For example, the specification describes gene sequences, corresponding sequences from other species, mutated sequences, SNPs, polymorphic sequences, promoter sequences, exogenous sequences, and so forth (*see, e.g.,* specification at page 23, line 5 through page 30, line 6; and page 49, line 24 through page 56, line 24). The specification also describes appropriate hybridization conditions (*see, e.g.,* specification at 19, lines 5-18); nucleic acid molecules comprising nucleic acid sequences having conservative variations or encoding amino acid sequences having conservative substitutions (*see, e.g.,* specification at page 32, line 5 through page 33, line 10); fusion protein or peptide molecules or fragments thereof encoded by the nucleic acid molecules of the present invention (*see, e.g.,* specification at page 34, lines 18-24); nucleic acids comprising introns, intron/exon junctions, or both (*see, e.g.*, specification at page 33, lines 11-19); plant homologue proteins (*see, e.g.,* specification at page 34, line 25 through page 35, line 13); site directed mutagenesis of the claimed nucleic acid molecules (*see, e.g.,* specification at page 59, line 11 through page 60, line 27); and vectors comprising the claimed nucleic acid molecules and methods of transforming plants (*see, e.g.,* specification 61, line 1 through page 75, line 12). Despite the numerous variations described for the claimed nucleic acid molecules in the present specification, the Examiner maintains that "the written description requirements have not been adequately met for the broadly claimed genus of homologues, splice, mutant and polymorphic variants of SEQ ID NO: 1." Final Action at page 16.

The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids can be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description. For example, Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 1, and complements and variants thereof. The respective common structural feature (*e.g.*, the nucleotide sequences of SEQ ID NO: 1 and their complements) is shared by every nucleic acid molecule in the claimed genera, and it distinguishes the members of the claimed genera from non-members.

In light of the detailed disclosure of the present application, one skilled in the art, after reading the present specification, would clearly know if a nucleic acid molecule contains one of the recited nucleotide sequences. Thus, pending claims 8-11 is supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed. Reconsideration and withdrawal are respectfully requested.

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,

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Thomas E. Holsten (Reg. No. 46,098)
David R. Marsh (Reg. No. 41,408)

ARNOLD & PORTER LLP
555 Twelfth Street, NW
Washington, DC 20004-1206
202.942.5000 telephone
202.942.5999 facsimile

Of Counsel
Lawrence M. Lavin, Jr.
(Registration No. 30,768)
Thomas E. Kelley
(Registration No. 29,938)
Monsanto Company